OmniSonics Medical Technologies, Inc
Robert A Rabiner
President

DEC - 6 1999

K993445

510K Summary
OmniSonics Endoscopic Deflector

1. Sponsor Name

OmniSonics Medical Technologies
14 Equestrian Drive
North Reading, MA 01864

Telephone: (978) 664 8440
Contact Individual: Debbie Iampietro

2. Device Name

Proprietary Name: OmniSonics Endoscopic Deflector
Common/Usual Name: Endoscope
Classification Name: Endoscope and accessories

3. Identification of Predicate or Legally Marketed Device

The OmniSonics Endoscopic Deflector is substantially equivalent to several legally marketed devices in intended use, design and technological characteristics. Those devices to which it is substantially equivalent are: Omnisonics Endoscopes (K991377), Karl Storz Hystero-Fiberscope (K990411), Karl Storz Laser Application Instrument (K# unknown), and the Naviport Deflectable Tip Guiding Catheter (K974683).

4. Device Description

Principle of Operation

The OmniSonics Endoscopic Deflector assists in the delivery of small diameter flexible, instruments, catheters, probes, and endoscopes. The device deflects these instruments to aid in the direction and delivery of the product to a specific surgical site that is not in line with the axis of the instrument. The purpose of the OmniSonics Endoscopic Deflector is to provide a means to deliver small diameter instruments to areas that would be difficult to access with a straight instrument.

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The OmniSonics Endoscopic Deflector works in a similar fashion to steerable endoscopes. This instrument is different in that it only contains lumens for the introduction of ancillary instrumentation and does not possess an integral visualization system. The user must insert all of the additional capabilities desired through the OmniSonics Endoscopic Deflector central lumen.

Products that are capable of working with the OmniSonics Endoscopic Deflector are flexible, malleable or bendable and must be capable of obtaining a bend radius of 30 mm or less. They must also have an outer diameter compatible with the inner diameter of the unit selected. The actual deflection produced at the end of the device will depend upon the stiffness of the inserted instrument.

Device Configuration and Materials

The OmniSonics Deflector is constructed with the following major components:

Outer sheath tube:	A rigid, stainless steel tube that provides rigidity for insertion into the body
Deflection tube:	A flexible, polyurethane, kink resistant tube that bends when the deflection handle is activated.
Deflection wire:	A stainless steel wire that pulls the tip of the deflection tube to cause deflection.
Deflection handle:	An ABS handle that has mechanisms for rotation of the shaft, articulation of the deflection tube, movement of the inserted device in and out and sealing of the inserted device.

5. Intended Use

Intended use

The OmniSonics Endoscopic Deflector is a device designed to assist in the placement and deflection of small diameter malleable instruments, catheters and endoscopes used in surgical procedures in body cavities, hollow organs and canals.

The OmniSonics Endoscopic Deflector is designed to be introduced through natural body openings, surgical incisions and through introducers, needles, trocars, catheters, sheaths and other devices with lumens having an inside diameter larger than the outside diameter of the OmniSonics Endoscopic Deflector shaft selected. The OmniSonics Endoscopic Deflector is sold sterile and is intended for single patient use. The OmniSonics Endoscopic Deflector is indicated for the following applications:

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Ureteroscopy
Thoracoscopy
Nasopharyngoscopy
Sinuscopy
General laparoscopy
Urology
Gynecology
Bronchoscopy

6. Comparison of Technological Characteristics

All of the predicate devices are similar in intended use, design and materials. The proposed OmniSonics Endoscopic Deflector is made materials that have been widely used in other endoscopic applications and have a long history of use.

All of the predicate devices offer various configurations, lengths, diameters, and have varying degrees of deflection. The proposed OmniSonics Endoscopic Deflector's specifications are similar to the parameters established by the predicate devices and similar to other devices in the medical device industry.

The technological characteristics used in the proposed OmniSonics Endoscopic Deflector to assist in the placement, deflection and/or articulation of medical devices into body cavities, hollow organs and canals are inherent in the predicate Karl Storz Laser Application Instrument and the Naviport Deflectable Tip Guiding Catheter.

The difference in technological characteristics is in the generic application of the OmniSonics Endoscopic Deflector. Each of the predicates and devices cited for similarities in deflection capability are "dedicated" to the devices they accompany. The OmniSonics Endoscopic Deflector is not dedicated to one instrument or corporate family of instruments. It is to be used with other devices that are compatible to its design characteristics as identified in its labeling.

Since the OmniSonics Endoscopic Deflector is the same in intended use, design, principle of operation, technological characteristics, and materials as the predicate devices, the OmniSonics Endoscopic Deflector does not raise any new safety and efficacy concerns when compared to these similar legally marketed devices. Therefore, the OmniSonics Endoscopic Deflector is substantially equivalent to these existing devices.

7 Performance Testing
The OmniSonics Deflector conforms to IEC 60601-18
All materials used are biocompatable

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 1999

OmniSonics Medical Technologies, Inc.
c/o Ms. Debbie Iampietro
QRC Consulting
7 Tiffany Trail
Hopkinton, Massachusetts 01748

Re: K993445
Trade Name: Endoscopic Deflector
Regulatory Class: II
Product Code: KOG
Dated: October 8, 1999
Received: October 12, 1999

Dear Ms. Iampietro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993445

Device Name: OmniSoncis Endoscopic Deflector

Indications For Use:

The OmniSonics Endoscopic Deflector is designed to assist in the placement and deflection of small diameter malleable instruments, catheters and endoscopes used in surgical procedures in body cavities, hollow organs and canals.

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Ureteroscopy
Thoracoscopy
Nasopharyngoscopy Sinuscopy
General laparoscopy
Urology
Gynecology
Bronchoscopy

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993445

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